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K120770

DEC 0 6 2012

GE Healthcare
510(K) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	March 9, 2012
Submitter:	GE Healthcare (GE Medical Systems *Information Technologies*) 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Kristin Pabst Regulatory Affairs – Diagnostic Cardiology 9900 Innovation Drive Wauwatosa, WI 53226 T: (414) 721-3104 F: (414) 721-3863
Secondary Contact Person:	Doug Kentz Regulatory Affairs Director 9900 Innovation Drive Wauwatosa, WI 53226 T: (414) 362-2038 F: (414) 362-2585
Device: Trade Name:	QT Guard Plus Analysis System
Common/Usual Name:	ECG Analysis Program
Classification Names:	Monitor, Physiological, Patient (with arrhythmia detection or alarms)Programmable Diagnostic Computer
Product Code:	MHX 21CFR 870.1025 DQK 21CFR 870.1425
Predicate Device(s):	K981024; QT Dispersion and T Wave Analysis Program (QT-Guard Analysis System) K072502 MUSE Cardiology Information System
Device Description:	QT Guard Plus is a software program that runs on a Microsoft Windows PC-based platform and utilizes 12 lead data from GE's 12SL ECG Analysis Program (K092369) to measure QT and T Wave measurements for clinical or scientific investigation. The program analyzes simultaneously acquired digital 12 lead ECGs that have been previously acquired by other ECG acquisition and storage devices. QT Guard Plus does not directly acquire data from a patient. The program has a user interface that displays the ECG along with the measurements generated by the program. These measurements can be modified via the user interface.
Intended Use:	QT Guard Plus Analysis System is intended to be used in a hospital, clinic or research environment by competent health professionals. QT Guard Plus Analysis System is intended to perform the analysis of simultaneously acquired 12-lead ECGs for obtaining the measurement

of QT interval dispersion and T wave complexity.
QT Guard Plus Analysis System is intended to provide only the measurements of the QT dispersion and T wave complexity and is not intended to produce any interpretation of those measurement or diagnosis.
The QT dispersion and T wave complexity measurements produced by QT Guard Plus Analysis System are intended to be used by qualified personnel in evaluating ECG data and the patient in conjunction with patient's clinical history, symptoms other diagnostic tests, as well as the professional's clinical judgment.

QT Guard Plus Analysis System is intended for adult patient populations.

Technology: QT Guard Plus employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence: Summary of Non-Clinical Tests:

There are no recognized consensus standards applicable to QT Guard Plus Analysis System. QT Guard Plus and its applications comply with the Guidances and/or Special Controls as detailed in Section 9 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Requirements Reviews
- Risk Analysis
- Software Verification and Validation
- Performance testing

Summary of Clinical Tests:
The subject of this premarket submission, QT Guard Plus did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers QT Guard Plus Analysis System to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

DEC 0 6 2012

GE Healthcare Systems Information Technologies
c/o Kristin Pabst
9900 Innovation Drive
Wauwatosa, WI 53226

Re: K120770
Trade/Device Name: QT Guard Plus Analysis System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph.
Regulatory Class: Class II (two)
Product Code: DPS, MLC
Dated: November 14, 2012
Received: November 15, 2012

Dear Ms. Pabst:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mitchell J. Shein
2012.12.06
11:44:40 -05'00'

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120770

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GE Healthcare
510(K) Premarket Notification Submission

510(k) Number (if known):

Device Name: QT Guard Plus Analysis System

Indications for Use:

QT Guard Plus Analysis System is intended to be used in a hospital, clinic or research environment by competent health professionals.
QT Guard Plus Analysis System is intended to perform the analysis of simultaneously acquired 12-lead ECGs for obtaining the measurement of QT interval dispersion and T wave complexity.

QT Guard Plus Analysis System is intended to provide only the measurements of the QT dispersion and T wave complexity and is not intended to produce any interpretation of those measurement or diagnosis.
The QT dispersion and T wave complexity measurements produced by QT Guard Plus Analysis System are intended to be used by qualified personnel in evaluating ECG data and the patient in conjunction with patient's clinical history, symptoms other diagnostic tests, as well as the professional's clinical judgment.

QT Guard Plus Analysis System is intended for adult patient populations.

Prescription Use_X___ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use__ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

12/6/2012

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120770